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CORRESPONDENCE

CE Mark for Iliac Stents

Peter Gaines is to be thanked for drawing our attention to his concerns regarding the CE marking for iliac stents (EJVES 29, 105 (2005)).

I think his comments are not confined solely to iliac stents but indeed also apply to a number of other cardiovascular implants. As I have been personally involved with BSI (British), CEN (European), and ISO (International) Committees writing standards for cardiovascular implants for many years I do understand and share many of his concerns regarding the standard of uniformity of Notified Bodies throughout the EU who can grant a CE mark to manufacturers for their products and the sometimes lack of adequate mandatory pre- and post-market surveillance of implants especially when modifications are made to existing implants. Whereas for manufacturers to obtain a CE mark for their cardiovascular implants, if to be used within the European Union is, by European law, mandatory, sadly the use of a CEN Standard to obtain the CE mark, is not. Any standard or literature to support their application can be used and is often submitted. I can assure Gaines that I and all of my European clinical colleagues have for years fought and to a large extent succeeded in writing into the present CEN Standards clauses to ensure that appropriate pre- and post-marketing studies are carried out. Also a great strength of the CEN Standard is the section of pre-clinical evaluation bench and analytical tests which are required to be carried out. The constant debate at standards committee meetings is the clinicians would like to see a time frame of pre- and post-market surveillance which would result in the project being financially non viable to manufacturers. However, I have frequently reminded manufactures that they are potential patients too! The present ISO Standard for Endovascular prostheses has a robust section for pre- and post-market surveillance but the standard is not mandatory for manufactures to use. However, as many of these services are manufactured in the USA it would not be surprising if the FDA use the present ISO standard as a vital yardstick. Certainly, the ISO standard on vascular stents at present in preparation will be strong in pre- and post-market surveillance requirements.

CEN and ISO work very closely together and a number of their standards have been harmonised over the years, so hopefully one day, it would be mandated that all companies worldwide must comply with the harmonised CEN/ISO standards. In the meantime, it behoves all implanters to ask the manufacturer what pre- and post-market studies have been performed on their implants and also specific to the UK inform the Medicines and Healthcare Products Regulatory Agency (MHRA) in London of any adverse invents involving any cardiovascular implant. I can also assure Gaines that as a result of pressure mainly from the UK regarding our concern over the lack of clinical data supporting the CE marking of some devices that a Commission Task Force has been formed which has already produced a number of guidance documents for Notified Bodies to use and this issue is also being monitored by the Notified Bodies Oversight Group which is at present chaired by the UK.

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